K093537
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510(K) SUMMARY

JUN - 4 2010

[as required by 807.92(c)]

2010. April.23

A.510k Number:

B. Applicant:

Company name: PATS CORP

Contact Person: Brandon Choi

Address: 49 Candlewood Way, Buena Park, CA 90621, USA

Phone: 714-523-1592 Fax: 714-523-1592

C. Proprietary and Established Names: M. I. Tech Co., Ltd

Address: 241-3 Habuk-ri, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do 451-864 KOREA

D. Regulatory Information

- Classification Name: prosthesis, esophageal
- Common / Usual Name: esophageal stent
- Proprietary Name: HANAROSTENT® Esophagus (CCC)
- Classification / Product Code: Class II / ESW (21 CFR 878.3610)

E. Indication for use

HANAROSTENT® Esophagus (CCC) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula.

F. Description of the Device:. HANAROSTENT® Esophagus (CCC) is a self-expanding polygon mesh surface, tubular prosthesis designed to maintain patency of esophageal strictures caused by malignant tumors. The stent is made of Nitinol wire (hook and cross wire structure) and a silicon membrane designed in such a way as to prevent migration and tumor in-growth. The stent is symmetrical in shape, with the diameter of both ends of the stent extending beyond the diameter of the stent body (larger banded flanges). This band design has become standard practice and aids in preventing stent migration.

G. Safety and Effectiveness, comparison to predicate device.

The results of bench and test laboratory testing indicate that the new device is as safe and effective as the predicate devices.

Product name Feature	HANAROSTENT® Esophagus (CCC)	Choostent™ covered Esophageal Stent	UltraflexTM Esophageal NG Stent System
510(k) No.		K072094	K032930
Intended Use	HANAROSTENT® Esophagus (CCC) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula.	The CHOOSTENT™ covered esophageal stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and or extrinsic malignant tumors only and occlusion of concurrent esophageal fistula.	The UltraflexTM Esophageal NG Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and, for occlusion of concurrent esophageal fistula (for covered stents only).
Protheses configuration	Fully coated	Fully coated	Same
Coating material	Silicon	Silicone	Silicone
Stent diameter (mm)	Diameter : 18 / 22mm	18mm	Diameter : 23mm
Stent length (mm)	Length : 80 / 170mm	80-170	Length : 100 / 120mm
Delivery diameter	Diameter : 6mm	Diameter : 6mm	
Expansion Force	0.94/0.79 lbs	0.83	
Compression force	1.88 lbs	2lbs	
Corrosion (in simulated gastric fluid)	> 18days	>18days	
Tensile strength	>15 lbs	>15 lbs	

H. Conclusion

The HANAROSTENT® Esophagus (CCC) has substantial equivalent intended use as the-market cleared K072094, K032930 and has substantial equivalent technological and performance characteristics. After analyzing both bench as well as laboratory testing to applicable standards, it is the conclusion of M. I. Tech Co., Ltd. that the HANAROSTENT® Esophagus (CCC) is as safe and

effective as the predicate devices, it has few technological differences, but there are no new indications for use and without raising any new safety and/or effectiveness concerns.
Consequently, it is clear that it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

M.I. Tech Co., Ltd.
c/o Brandon Choi,
General Manager
PATS CORP
49 Candlewood Way
BUENA PARK CA 90621

JUN - 4 2010

Re: K093537
Trade/Device Name: HANAROSTENT® Esophagus (CCC)
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: April 27, 2010
Received: May 6, 2010

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

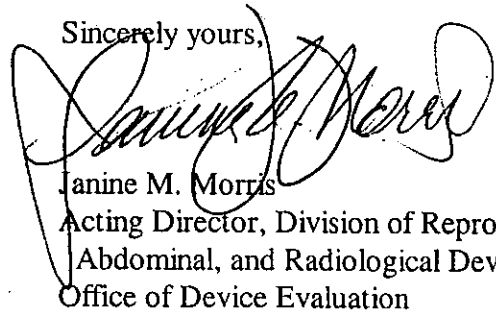
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093537

Device Name: HANAROSTENT® Esophagus (CCC)

Indications For Use: HANAROSTENT® Esophagus (CCC) is intended for maintaining esophageal luminal patency inesophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093537